## Formulary Submission Form

Use this Form to apply for:

* Approval for a new drug (or new presentation) to be added to the formulary, or
* Approval for variation to an existing formulary listing, or
* Approval for use of a drug under other circumstances (eg patient familiarisation program).

For approval to use this drug ion an individual patient basis, use the IPU application form.

# Product Profile

|  |  |
| --- | --- |
| Australian Approved (generic) Name | Cinacalcet |
| Trade Name | Sensipar |
| Dosage Form(s) – provide full details | 30, 60, 90mg tablets |
| Manufacturer/Supplier | Amgen Australia PL |
| Pharmacological class and action (summary) | Calcimimetic, hypocalcaemic |

# Indication(s) for use

Is the drug approved by the Therapeutics Goods Administration (TGA) for marketing in Australia?

Yes  No

What are the proposed indications for drug use in the hospital?

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| --- |
| Hypercalcaemia in primary hyperparathyroidism due to parathyroid adenoma or hyperplasia in patients who satisfy crieteria but are unsuitable for parathyroid surgery. Current criteria for surgery are: serum calcium > 0.25mmol/l above upper limit of normal; creatinine clearance < 60mmol/l; osteoporosis defined as T score < 2.5 at any site and/or previous fragility fracture; and age <50 years.  Hypercalcaemia in parathyroid carcinoma |

Is this a TGA approved indication?  Yes  No

Is the drug already listed on the hospital formulary for other indications?  Yes  No

If **YES**, list current formulary approval (including restrictions):

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| Secondary hyperparathyroidism in patients with end stage renal disease, receiving dialysis |

### PBS Listing

Is the drug listed as a benefit under the Pharmaceutical Benefits Scheme?  Yes  No

If **YES**: Section 85?  Yes  No Section 100?  Yes  No

Is the proposed hospital indication approved for subsidy under the PBS?  Yes  No

If no, explain implications for continuity of supply. (Will the drug be supplied for inpatient use, outpatient use or both? Will the hospital be required to provide ongoing therapy after discharge?)

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| Drug will be supplied for inpatient use. Funded outpatient use will require an Individual Patient Use (IPU) application, except in the following circumstances:  Indications for use without an IPU:  Patient at least 70 years old  AND Corrected Calcium over 0.25mmol/l above upper limit of normal on two occasions a month apart or calcium over 3.0mmol/l on two occasions (any time interval)  AND Patient unsuitable for surgery  AND Patient under the care of an endocrinologist or renal physician  OR Patients with hypercalcaemia due to parathyroid carcinoma - all ages and calcium levels |

**Reasons for Request**

**Cross**

Addition to the formulary

Change in formulary approved use

Addition of a new form or presentation of existing product

Other (eg familiarisation program)

Explain your reasons for wanting to use this drug.

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| There are no satisfactory medical treatment options in patients who are unsuitable for surgery, who have hypercalcaemia secondary to severe primary hyperparathyroidism or parathyroid carcinoma. Intravenous bisphosphonates are less effective and only give temporary relief for several weeks and require frequent monitoring and inpatient/HITH administration. |

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| **Treatment details:**  Recommended dose, administration details, duration of treatment, etc | **30mg bd orally. Dose titrated every 2-4 weeks in increments of 30mg bd, to a maximum of 90mg QID. Treatment duration indefinite.** |
| List drugs recommended for co-administration or used in combination. | **Nil** |
| **Relevant comparator(s):**  Describe the therapy currently used for this indication, if any: | **Intravenous Pamidronate or Zoledronate** |
| If this drug is added to the formulary, which drug(s) should be deleted? |  |
| **Monitoring requirements:**  Describe the objective criteria that will be used to monitor effectiveness. | **Serum calcium. Should achieve level at least 2.5mmol/l below upper limit of normal** |
| **Proposed place in therapy:**  Describe the investigations necessary for patient selection and treatment. | **Elevated corrected serum calcium and parathyroid hormone. Creatinine clearance, serum creatinine, eGFR. Bone density by DEXA scan** |
| Which patient groups are most likely to benefit? | **Patients with significant co-morbidities, elderly patients** |
| Will this drug be used as first, second or third-line therapy? | **First-line - if surgery not feasible** |
| What prescribing restrictions should be in place (eg medical officers authorised to prescribe)? | **On recommendation of consultant in charge of patient** |

**Attach details of proposed prescribing criteria, guidelines and/or protocols** (see prescribing protocol template for guidance about the details required).

Other supporting documentation should also be attached (eg consensus guidelines, approval by overseas agencies, published data, clinical trial data, etc).

**Comparative Safety and Efficacy**

Include names of comparators. If necessary, attach additional information as a separate document.

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| --- | --- | --- | --- | --- |
| **Significant side effects\*** | **New Drug:** |  | **Current therapy:** |  |
| **Common:** *(ie incidence of 1% or more)* | Fatigue, headache, depression, hypocalcaemia, nausea, vomiting, diarrhoea, anorexia, constipation, parasthesiae | | Fever, flu-like symptoms, hypocalcaemia, hypophosphataemia, anaemia, hypertension, headache, paraesthesiae, injection site reactions | |
| **Infrequent:** *(ie incidence between 0.1% and 1%)* | Seizures | | Abnormal LFT, hypotension, lethargy, seizures, acute renal failure | |
| **Rare:** *(ie incidence less that 0.1%)* | Cardiac arrhythmia, hypersensitivity | | LV failure, confusion | |

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| **Main Benefit in Safety\*** | **New Drug:** |  | | **Current therapy:** |  | |
| Incidence of main adverse event expressed as a percentage. *Specify (eg stroke, mortality, allergic reaction, etc).* | 30% | |  | 30% | |  |
|  | Nausea | | | Fever, flu-like symptoms | | |
| Level of evidence (see page 5) | I | | | I | | |

|  |  |  |  |  |  |  |
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| **Main Benefit in Effectiveness\*** | **New Drug:** |  | | **Current therapy:** |  | |
| Incidence of main effectiveness outcome measure expressed as a percentage. *Specify outcome measure (eg cure rate, relapse rate) and whether measure represents a surrogate marker or an actual health outcome.* | 73% | |  | 0% | |  |
|  | Normalisation of serum calcium in placebo-controlled double blind trial, versus 5% with placebo. Level II evidence | | | Pamidronate did not normalise serum calcium un uncontrolled study. Mean levels 2.84 pre-treatment, minimum 2.63 at day 6, 2.75 at day 30. Level IV evidence | | |
| Level of evidence (see page 5) |  | | |  | | |

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| --- | --- | --- | --- | --- |
| **Additional benefits\*** | **New Drug:** |  | **Current therapy:** |  |
| *Specify (eg surgery or procedure averted, admission averted, reduced length of stay, etc).* | Avoidance of admissions with acute hypercalcaemia and HITH/inpatient administration of intravenous bisphosphonate. Less frequent monitoring of serum calcium. | | Only suited to acute setting. | |

**\* Reference the sources used for the above data. Literature references should cite the primary clinical trials(s).**

**Comparative costs of drug treatments:**

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| --- | --- | --- | --- | --- | --- | --- |
|  | **New** | | **Current (1)** | | **Current (2)** | |
| *Include the name of comparators:* |  | | **No suitable medical comparator** | |  | |
| 1. Average dose per day |  | |  | |  | |
| 1. Average duration of treatment in days |  | |  | |  | |
| 1. Average number of dosage units per day |  | |  | |  | |
| 1. Cost per dosage unit | $ |  | $ |  | $ |  |
| 1. Cost per standard course *(b x c x d)* | $ |  | $ |  | $ |  |
| 1. Additional costs per patient per course *(eg additional drugs, monitoring requirements, etc)* | $ |  | $ |  | $ |  |
| 1. Total annual costs per patient *(e + f)* | $ |  | $ |  | $ |  |
| 1. Expected number of patients per year *(include the basis for this estimate)* |  | |  | |  | |
| 1. Annual cost *(g x h)* | $ |  | $ |  | $ |  |
| 1. Difference *(new cost – current cost)* | | | $ |  | $ |  |
| 1. Cost offsets if the new drug were introduced: | | | | | | |
|  | | | | | | |
| 1. Proposed source of funding: | | | | | | |
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**Issues Regarding Safe Administration:**

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| **Product packaging and Labelling** eg, Is product nomenclature likely to lead to confusion in selection? Is packaging clearly labelled? Is each dosing unit labelled in such a way to allow identification up to the point of administration? Does packaging facilitate clear and practical storage? Is appropriate Consumer Medicines Information available? |
| N/A |
| **Administration** eg, Are physical incompatibilities likely in the administration of the product? Are the potential adverse events associated with administration techniques? What are the nursing implications of product preparation and/or administration requirements?  Monitoring for hypocalcaemia required |
|  |

**Details of Applicant**

**Requested by:**

|  |  |  |  |
| --- | --- | --- | --- |
| Name of Applicant | Robert Schmidli | | |
| Position / Appointment | Senior staff specialist | | |
| Signature |  | Date |  |

**Endorsed by:**

|  |  |  |  |
| --- | --- | --- | --- |
| Name of Unit Head | Dennis Wilson | | |
| Position / Appointment | Director, department of Endocrinology | | |
| Signature |  | Date |  |

**Conflicts of interest**

Financial or other interests resulting from contact with pharmaceutical companies, which may have a bearing on this submission:

Gifts  Industry paid food/refreshments

Travel expenses  Honoraria

Samples  Research support

Other support (describe) …………………………………………………………………………………

### Now complete checklist ▶

**Cross**

All sections of form completed (including assessment)

Supporting data attached (relevant papers, consensus guidelines, etc)

Prescribing criteria / protocol / guideline attached

#### ▶ Forward completed from to pharmacy

|  |  |
| --- | --- |
| Grading for Level of Evidence\* | |
| Level 1 | Evidence obtained from systematic review of relevant randomised controlled trials |
| Level II | Evidence obtained from one or more well-designed, randomised controlled trials |
| Level III | Evidence obtained from well designed, non-randomised controlled trials, or from well designed cohort, case control or interrupted time series studies |
| Level IV | Case series with either post-test or pre-test/post-test outcomes |
| \* From NHMRC interim levels of evidence 2005: www.nhmrc.gov.au/publications/\_files/levels\_grades05.pdf | |

## For Drug and Therapeutics Committee Use Only

**Comparative Approvals:**

Has this drug been considered for formulary approval by other DTCs in NSW hospitals?  Yes  No

If **YES**, list relevant DTCs and their decisions. (NB information available via NSW TAG)

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**Outcome of application process:**

|  |  |  |
| --- | --- | --- |
| **Process** | | **Date / Details / Notes** |
| Application received *(Date received by DTC secretary)* | |  |
| Application considered *(DTC meeting date)* | |  |
| Outcome: | Approved |  |
|  | Rejected |  |
|  | Deferred |  |
| Conditions of approval *(Specify restrictions)* | |  |
| Approval review date *(if applicable)* | |  |
| Applicant advised of outcome *(Date)* | |  |

Signed on behalf of Drug and Therapeutics Committee: \_     \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_     \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_